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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,318	10/23/2001	Brian M. Sullivan	38-0011	8012

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,318	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 23, 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claim 2 is objected to because of the following informalities: It is unclear is claim 2 is an independent claim or a dependent claim. It appears that claim 2 should depend from claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1 the recitation "the method" there is insufficient antecedent basis for this limitation.

Claim 1, line 2 the recitation "plurality of 2^N-1 bioagents" is vague and indefinite. It is unclear if applicant is identifying many of the same type of bioagents or different types of bioagents.

Claim 1, line 8 "plurality of N detection processes" is vague and indefinite. It is unclear if applicant is using many different detection process or many of the sample detection process to detect a bioagent. For example is one detection process a raman spectroscopy detection process and a second detection process a competitive

immunoassay detection process. Or is applicant using the same type of detection process to determine a different bioagent in each divided sample.

Claim 1, line 9 the recitation "employing" is vague and indefinite. It is unclear how a molecular interaction is used to identify a bioagent.

Claim 1, line 10 the recitation "possessing a capability" is vague and indefinite. Does the separate detection processes detect a bioagent from a collection of known bioagents or not? Further, it is unclear what capability applicant is referring to.

Claim 1, line 11, "known bioagents" is vague and indefinite. It is unclear if these known bioagents are the bioagents recited in line 2 or if they are different bioagents.

Claim 1, line 11 "known bioagents" is vague and indefinite. Is applicant incorporating a standard or control into the method.

Claim 1 is vague and indefinite because it is unclear why applicant has one more bioagent than a detection process and only determines one bioagent. For example, if N=2, there are 3 bioagents and 2 detection processes to determine only one bioagent. It is unclear with respect to more than two unknown bioagents. If 3 bioagents, how are they determined if only two separations are performed. Does each of the divided samples comprise all three bioagents. Please clarify.

Claim 8, line 8 the recitation "multiple bioagents" is vague and indefinite. It is unclear if applicant is referring to the plurality of bioagents recited in claim 1 or if applicant is referring to some other bioagents.

Claim 9, line 7 the recitation "multiple bioagents" is vague and indefinite. It is unclear if applicant is referring to the plurality of bioagents recited in claim 1 or if

applicant is referring to some other bioagents. See also deficiencies found in claim 10, 11

Claim 12 is vague and indefinite because of the use of acronyms: ie 2°, Ab-Enz, etc.... Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance. See also deficiency found in claim 15.

Claim 12 is vague and indefinite because claim 12 implies the use of a secondary antibody-enzyme conjugate. However, there is no primary antibody recited in the claims. It is unclear if there is a primary antibody applied in the process.

Claim 15, line 1 "the method" there is insufficient antecedent basis for this limitation.

Claim 15, line 2 the recitation "plurality of 2^N-1 bioagents" is vague and indefinite. It is unclear if applicant is identifying many of the same type of bioagents or different types of bioagents.

Claim 15, line 10 the recitation "the representative ELISA process" there is insufficient antecedent basis for this limitation.

Claim 15, line 10 "the representative ELISA process" is vague and indefinite. It is unclear which process applicant is referring to.

Claim 15, line 10 "is able to detect" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. Does the ELISA process detect the bioagents or not.

Claim 15, line 11 the recitation "possessing a capability" is vague and indefinite. Does the ELISA processes detect a bioagent from a collection unique bioagents or not? Further, it is unclear what capability applicant is referring to.

Claim 15, line 12 the recitation "unique collection" is vague and indefinite. It is unclear what applicant intends. Further, it is unclear how the bioagents are unique.

Claim 15 is vague and indefinite because claim 15 implies the use of a secondary antibody-enzyme (2° Ab-Enz) conjugate. However, there is no primary antibody recited in the claims. It is unclear if there is a primary antibody applied in the process.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 2, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Walt et al (US 6,023,540).

Walt et al disclose a method to determine an analyte of interest amongst a plurality of analytes. Walt et al disclose individual beads fixed into individual wells (N parts) are contacted with a sample (ie each individual well receives a part of the sample). Walt et al disclose that the beads in each well contain a chemical functionality (bioagent) for a known analyte collection (col 9 – col 10, Figure 3). Walt et al disclose collectively determining the results and determining an analyte of interest.

5. Claims 1-6 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Shipwash (US2002/0058273).

Shipwash disclose a method of determining the existence of and identifying an analyte of interest. Shipwash disclose applying a sample to a microfluidic device, which divides the sample into an array of reaction chambers (Fig. 5B). Each chamber identifies a different analyte of interest (p. 38, paragraph 0430). Shipwash discloses performing a detection process using different reagents for each analyte of interest. Shipwash discloses that an ELISA format using primary and secondary antibodies can be used to determine the analyte of interest (p. 38). Shipwash discloses the secondary antibody is labeled with an enzyme. Shipwash discloses that the reaction may be monitored simultaneously, or nearly simultaneously or in parallel (abstract).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash.

See above for teachings of Shipwash.

Ship wash differ from the instant invention in failing to specifically teach a plurality of 2^N-1 bioagents in a sample containing a bioagent wherein the integer is 5.

With respect to integers as recited in the instant claims. One of ordinary skill in the art would select a particular number for the desired analyte and devise the appropriate amount of reaction chambers.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al in view of Van Chandler et al (US 5,981,180).

See above for teachings of Walt et al.

Walt et al differ from the instant invention in failing to teach comparing the test results to a chart.

Van Chandler et al disclose using beads and subsets of beads to determine an analyte of interest. Van Chandler et al disclose the use of charts to determine the analyte of interest. Van Chandler et al disclose that these computations provides an improved data classification and analysis methodoly that enables the meaningful analysis of highly multiplexed assays in real-time (col 3).

It would have been obvious to one of ordinary skill in the art to incorporate charts to determine the analyte of interest as taught by Van Chandler et al into the method of Walt et al because Van Chandler et al shows that the use of charts provides for improved data classification and analysis of highly multiplexed assays in real-time.

Allowable Subject Matter

11. Claims 8-12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claim15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record neither teaches nor suggests a method of determining the existence of and identifying any one of a plurality of 2^N-1 bioagents in a sample containing a bioagent wherein the step of performing the separate identification process on each of the N parts includes the steps of:

Coating beads in N different collections and coating each collection of beads in the N different collections with receptor molecules for less than 2^N-1 plural bioagents but in which the N different collections contain collectively receptor molecules for all of the 2^N-1 plural bioagents, with one of the receptor molecules in each collection being a receptor for the same bioagent and with another of the receptor molecules in each collection being unique amongst the receptor molecules of all other collections; and applying the collection of coated beads in a respective one of the separate identification processes.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

McDevitt et al (US 6,680,206) disclose methods for determining an analyte of interest in multi-analyte fluids. McDevitt et al disclose a sample applied to a sensor array and the sample being divided into multiple cavities containing beads with immobilized receptors for capturing an analyte of interest.

Fritsch et al (US 2003/0077642) disclose ELISA assay utilizing immunobeads.

Macphee et al. (WO 99/07879) disclose an enzyme-linked immunoassay and electrochemical detection solid phase matrix (p 14). Macphee disclose performing two different ELISA processes on a divided sample (Fig 5).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
January 26, 2004

LONG V. LE
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02/4/04